

PSJ3  
Exhibit 392

## Updated 2008 GOALS

**EMPLOYEE:** Anita T. Ducca  
**POSITION:** Senior Director, Regulatory Affairs & Healthcare Policy  
**FOR PERIOD:** January 1, 2008 – December 31, 2008

### JOB ELEMENTS:

1. Strive to identify opportunities to incorporate of HDMA's position(s) on federal regulatory initiatives affecting the wholesale distribution industry. Work toward creating changes in federal regulatory requirements reflective of HDMA member's policy positions. 45%

### **SPECIFIC GOALS**

- Work toward identifying critical federal regulatory and related initiatives impacting the distribution industry, analyzing their impact, and toward development of strategies to support HDMA policies.
- DEA - Launch an initiative to proactively define DEA regulatory issues, develop policy positions and advocate such positions on behalf of HDMA's members. Includes, but is not limited to:
  - Suspicious Orders requirements and interpretations of implementing regulations
  - In-Transit Losses
  - Requirements for obtaining regulated sellers' self-certification numbers
  - Methadone
  - Iodine registration requirements
- Risk Management and Related Initiatives – Proactively identify and define FDA Risk Management and related regulatory issues, develop policy positions and advocate such positions on behalf of HDMA's members. Includes, but is not limited to:
  - Risk Management
  - Medication Guides
  - Electronic PIs
  - iPLEDGE
- As needed, strive to conduct appropriate follow-up interactions to further support written comments and oral testimony on the NDC rule particular regarding repackaging and definitions of relabeling.
- PDMA:

- Work with FDA staff to further clarify remaining questions and to seek revisions with respect to FDA's guidances (particularly the Q & A guidance issued in Nov. 2006) that are comparable to HDMA's prioritized positions.
  - Strive to develop and advocate regulatory policies and positions designed to implement legislation directing FDA to develop standards for unique identifiers.
  - Strive to develop and advocate HDMA policies and positions on FDA efforts to implement anticipated uniform (electronic) pedigree/track and trace legislation.
- Strive to enhance familiarity with, and conduct outreach to, key agency staff and stakeholders. Includes outreach among, senior and political appointee and other regulatory agency staff including staff of the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). Also includes staff of Trade Associations with interests in common to HDMA and its members (e.g., NACDS, NCPA, CHPA, etc.)
- Participate in additional HDMA committee meetings and seek to develop policies and communications regarding regulatory initiatives that require Government and Public Policy Council (GPPC) and the Government Affairs Committee (GAC) review/acceptance. Includes, but is not limited to, recommending regulatory policies and strategies for Committee consideration.

#### **Accomplishments for #1**

**Successfully launched and completed a comprehensive initiative to develop "Industry Compliance Guidelines" for reporting suspicious orders. Efforts included:**

- **Retained and managed a consultant and oversaw development of the ICG. Ensured committee reviews and follow-up revisions (RAC & GPPC) including a large face to face review meeting with HDMA RAC members.**
- **Discussed ICG with external stakeholders, including the DC-based Pain Care Forum on 1/11; and NACDS/NCPA/APhA Jan. 24 and Nov. 3.**
- **Worked with Outside Counsel and others to strategize DEA interactions, review, and final acceptance of the ICGs (3 DEA meetings total.)**
- **HDMA received a DEA letter of commendation on the ICG (October).**
- **Developed and provided a Webinar for HDMA members.**
- **Am currently planning follow-up including a DMC session.**

#### **Additional DEA efforts:**

- **Held a very successful meeting with Mark Caverly and additional DEA officials on July 17<sup>th</sup>. Discussed many DEA issues and HDMA members were very pleased with the meeting.**
- **Am currently preparing for a follow-up DEA meeting that we hope will take place early next year. Will stress "educating" DEA.**
- **I requested that DEA provide an update of the list of facilities eligible to receive Methadone 40 mg tablets under the Advisory. Received the list from DEA and arranged for communication to our members.**

- Presented HDMA's views on Controlled Substances before the APhA at the APhA Board of Trustees and Affiliated State Pharmacy Association Executives (ASPAE) Meeting (September 14).
- Oversaw the Manager of Regulatory Affairs efforts to
  - prepare comments on the DEA Form 222 proposed regulation, (We've heard that DEA is likely to back off of this proposal.)
  - summarize current security practices to prevent in-transit losses, and
  - prepare and communicate policy positions for the in-transit losses meeting at NABP.
- Identified the need for taking action on the final Iodine rule (which requires dual Controlled Substances and List I Chemical handler registration of distributors) and oversaw development of a "petition" requesting that DEA reopen the rulemaking comment period.

#### **FDA and Other Issues:**

Identified the need for responding to FDA's request for comments on implementing FDAAA's Risk Evaluation and Mitigation Strategies (REMS); managed OFW in preparation of comments; developed certain key policy elements for the comments. (Two sets of comments on REMS were prepared, one in the FDAAA 5-year plan which mentions REMS and the other in response to the Federal Register request for manufacturers to submit their REMS to FDA.)

Participated in the response preparation for FDA's request for comments on implementation of Technologies and Standards provisions in FDAAA (Section 913). Identified key policy approaches to address concerns with "validation" provisions.

Engaged in a conversation with FDA to find out what their plans are for the final NDC rule.

Oversaw the Manager of Regulatory Affairs review of the Single Patient Document Petition (i.e., the NACDS petition prepared by OFW to create an alternative to MedGuides) and submission of comments prepared by OFW on Paperwork Reduction Act elements of MedGuides.

Oversaw HDMA's participation in an HHS Import Safety Summit.

- Met with and developed relationships with representatives of allied trade associations (Bio, PhRMA, CHPA, GPHA) to discuss Medical Panel presentations, and with HHS representatives to plan the Summit (numerous meetings were held).
- Managed budget request for sponsorship.
- Reviewed and developed policies on HHS materials.
- Developed first draft talking points and Qs and As.
- Coordinated with appropriate HDMA and HHS staff.

Analyzed the WHO/IMPACT final draft Good Distribution Practices (GDP) Guidance. Identified numerous problem areas and notified the IFPW and FDA of appropriate corrections. (September 2008)

Submitted HDMA comments in response to FDA's request for information on the impact on availability of Dextromorphan (DEX) should FDA/DEA decide to schedule it as a controlled substance. (October 2008)

2. **Lead HDMA Regulatory Affairs Committee (RAC) and Regulatory Affairs and Healthcare Policy budget process activities, and participate in HDMA educational programs and HDMA committee management. 20%**

#### **SPECIFIC GOALS**

- Act as staff to the RAC. Strive to establish appropriate agenda, identify priorities for RAC consideration, and work with the committee to develop policies consistent with industry goals.
- Strive to identify at least one educational session for the Distribution Management Conference, solicit a speaker and work with the speaker to develop the session.
- Work towards establishing a federal Regulatory Affairs budget that adequately funds agreed-to priorities.
- Strive to administer of the Regulatory Affairs budget without exceeding budget allocations.

#### **Accomplishments for #2**

Coordinate two conference calls per month (develop agenda, identify issues, positions, etc.) and more as needed.

Develop policy positions on rulemakings and similar government initiatives (See specific issues identified under #1 above)

Track and communicate to membership developments in the RxUSA v. FDA lawsuit.

Involve Mark Caverly in DMC (Mark spoke on "A View from the DEA: Trends, Regulations & Interpretations"); similarly developed concept for David Durkin's presentation at DMC; and presented the Regulatory Affairs portion of the Pedigree Update panel at DMC.

Review/update financials monthly; currently developing 2009 budget.

3. **Work towards enhancing the Policy Development Program. 10%**

## **SPECIFIC GOALS**

- Work towards identification of issues critical to HDMA membership suitable for in-depth evaluation and analyses.
- Upon identification and agreement with GA Senior V.P., work towards identification of analytical mechanisms and/or expertise to address these issues within allocated budget. Determine suitable end products for use by HDMA and its members. Manage the analysis of identified issues and appropriate communication of final products.
- As priorities permit, act as principal liaison to the HDMA Healthcare Foundation on behalf of Government Affairs. Share information about upcoming GA activities as well as laws impacting HDMA members. Strive to collaborate with Foundation staff on economic or other industry analyses as appropriate.

### **Accomplishments for #3**

**Work on Policy Development has not been active primarily due to (1) higher priority issues particularly regarding DEA and (2) reduction in available budget for such activities.**

## **4. Supervise Manager, Regulatory Affairs including efforts to advance and support the HDMA/Regulatory Affairs objectives. 25%**

## **SPECIFIC GOALS**

- Provide oversight and guidance on designing strategies to ensure effectiveness of HDMA's advocacy efforts and on appropriate internal and external HDMA teamwork to address these issues.
- Provide guidance on updating and implementing the HDMA AMP Action Plan to address proposed and final AMP rule and on further developing the RSP (or other) alternative(s).
- Provide guidance on monitoring CMS regulatory initiatives, such as the Medicare Part B (ASP) activities and taking appropriate action if needed.
- Provide guidance on monitoring federal regulatory agency efforts to ensure distributor role in pandemic response efforts.
- Strive to continue development of the skills and performance of the Manager, Regulatory Affairs. Includes expanding the Manager's knowledge and responsibilities regarding federal regulatory initiatives beyond CMS to include FDA and DEA.

### **Accomplishments for #4**

*Goals Updated Nov. 2008*

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Oversaw the Manager of Regulatory Affairs' work efforts including outreach to other trade associations, appropriate identification and follow-up of issues, communication with HDMA members, policy development, budget preparation and financials assessments, and GPPC and Board preparations. Has included the Manager's development of comments and/or positions on:

- The DEA Form 222 proposed regulation,
- US Sentencing Commission's proposed amendments
- Interim final Medicaid rule "Multiple Source Drug Definition" (related to availability of the drug in the states for calculating AMP)
- Comments on the HHS Guidance on Pandemic Influenza Employer Antiviral Stockpiling
- The In-Transit Losses meeting at NABP

Identified issues, such as the proposed Physician Fee Schedule Rule containing ASP elements, and advised Manager, Reg. Affairs on conducting closer scrutiny to determine potential HDMA member impact.

For approximately 3 months, participated in "Coaching" sessions to enhance management and interactive skills. On a continuing basis have acted on suggestions designed to increase and enhance communications and to foster the relationship with the Manager, Reg. Affairs.

Working with the Coach, developed the "Performance Metrics" for Manager to identify performance duties and measures of success for the Manager to achieve during his probationary period.

Separately, developed a Performance Metric Chart as a tool to communicate with the Manager the critical job skills and performance characteristics needed to demonstrate that he was meeting HDMA's expectations at three levels of performance: "Minimum Requirements," "Satisfactory Plus," or "Associate Director" (i.e., promotable performance). HDMA's HR Director indicated she intended to use this chart as a template for defining performance and promotion expectations for other positions within HDMA.

Conducted Manager's Mid-year review. Included review of his updated Goals. I also revised his Job Description to clarify responsibilities. Comprehensively documented discussions, guidance provided, and the Manager's performance.

#### **SUMMARY OF GOALS/WEIGHTS**

Strive to identify opportunities to incorporate of HDMA's position(s) on federal regulatory initiatives affecting the wholesale distribution industry. Work toward creating changes in federal regulatory requirements reflective of HDMA member's policy positions. 45%

**Lead HDMA Regulatory Affairs Committee (RAC) and Regulatory Affairs and Healthcare Policy budget process activities, and participate in HDMA educational programs and HDMA committee management. 20%**

**Work towards enhancing the Policy Development Program. 10%**

**Supervise Manager, Regulatory Affairs including efforts to advance and support the HDMA/Regulatory Affairs objectives. 25%**